

**EFFICACY AND SAFETY OF TOPICAL ALPROSTADIL
CREAM (VITAROS®) IN
HYPERTENSIVE, DIABETIC AND CARDIAC PATIENTS
WITH MALE ERECTILE DYSFUNCTION (ED)**

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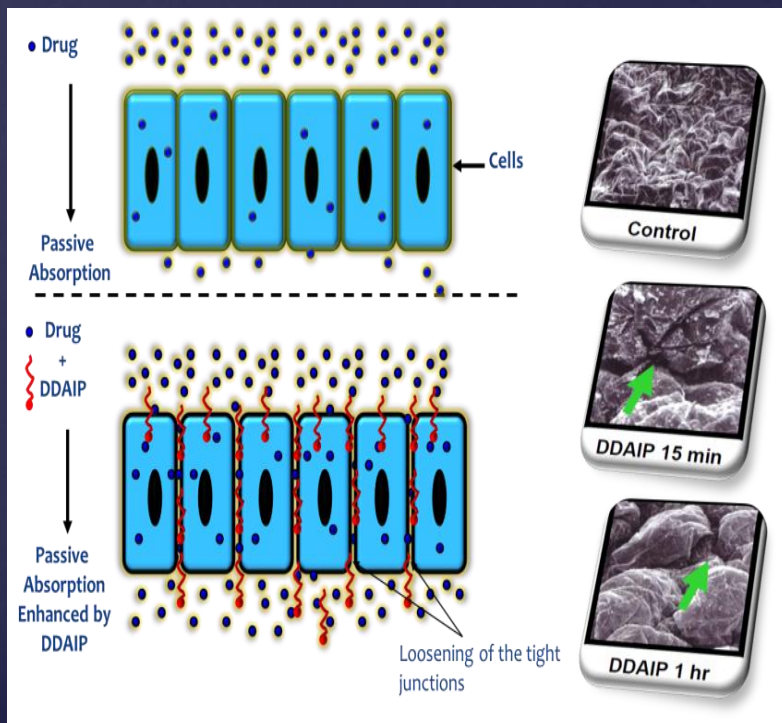
Oral Presentation: Dr. Jacques Buvat

ESSM, Milan, Italy, December 1, 2011

Convenient Topical Delivery of Alprostadil Cream (Alprostadil + DDAIP, Vitaros®)

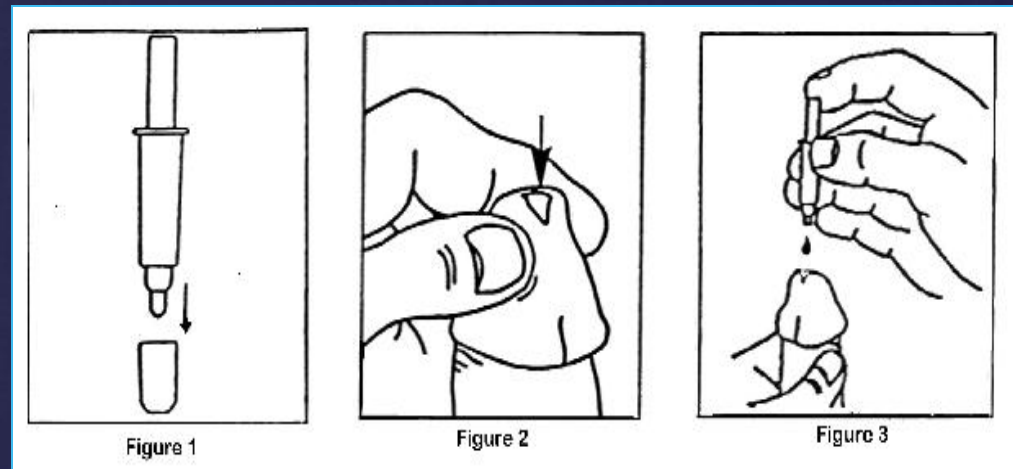
DDAIP is a novel penetration enhancer

It acts by loosening the tight junctions of the skin



Dosing Instructions

Single Dose (0.1ml cream) Dispenser

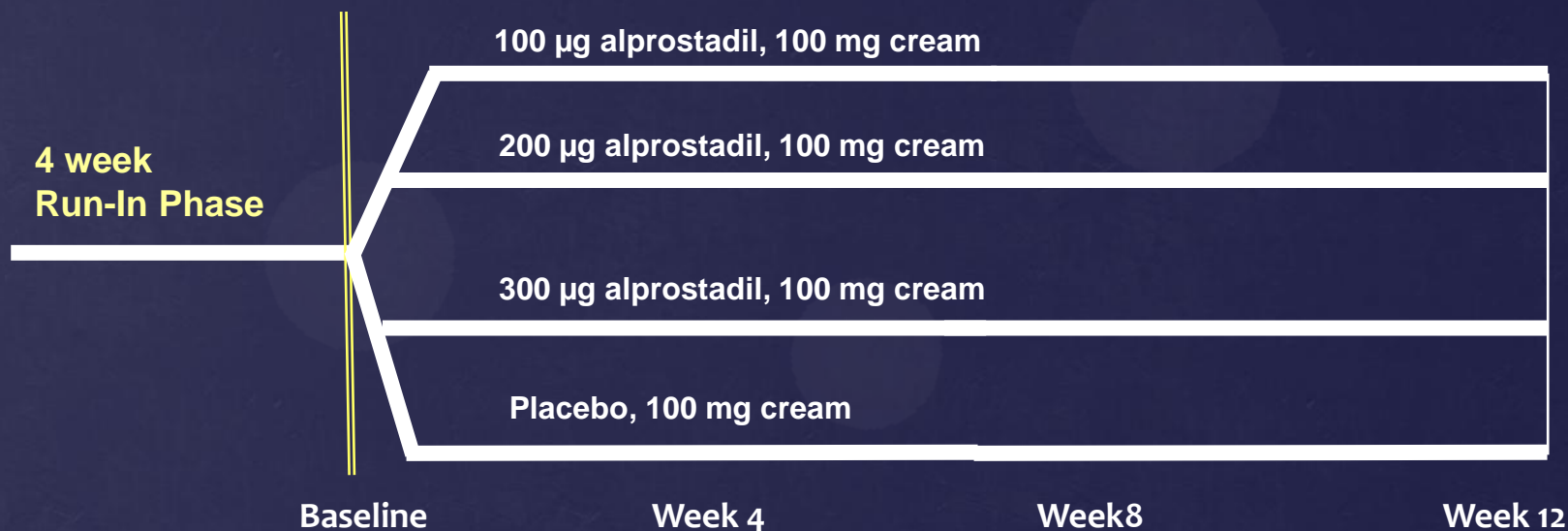


To be dispensed to tip of penis
in drop wise manner, not inserted

Integrates two multicenter, randomized, double-blind, placebo controlled trials with identical parallel groups design conducted at 82 sites in the USA (MED-2000-004/005)

Overall population: n= 1732 men with ED, 23 to 87 years old, mean age: 60.7 y

Population of this analysis: Men with Hypertension (n= 783, mean age: 62.9 y), Diabetes:(n= 382, mean age= 59.4 y), Cardiopathy (n=503, mean age: 64.5 y)



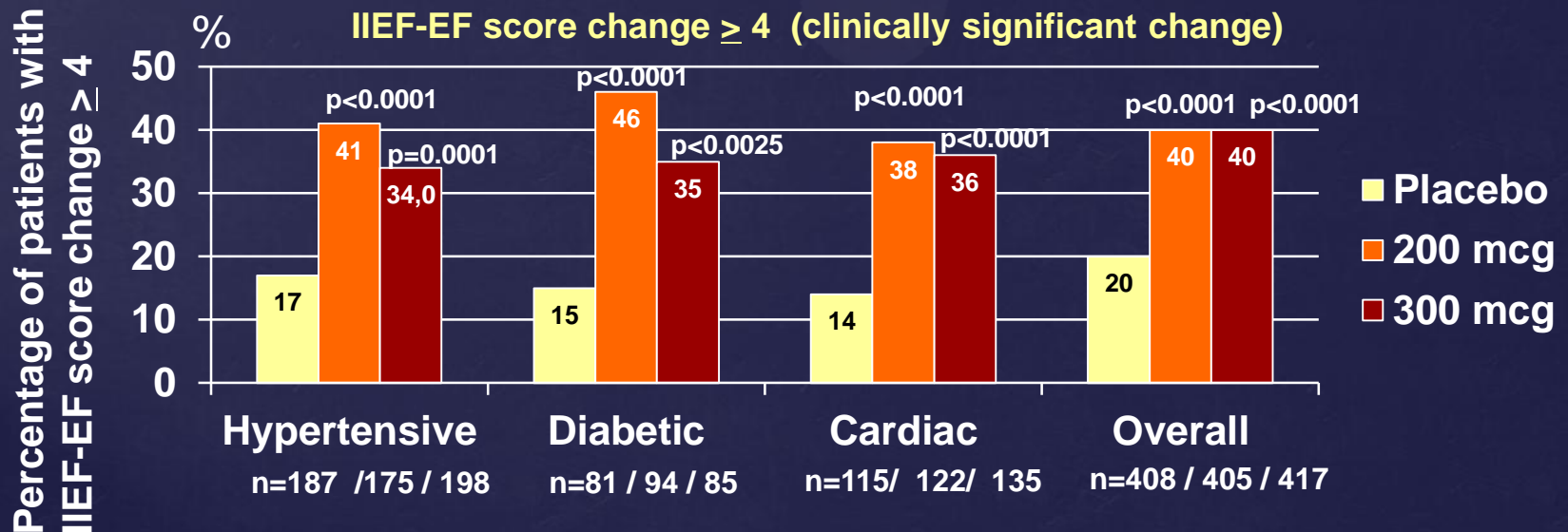
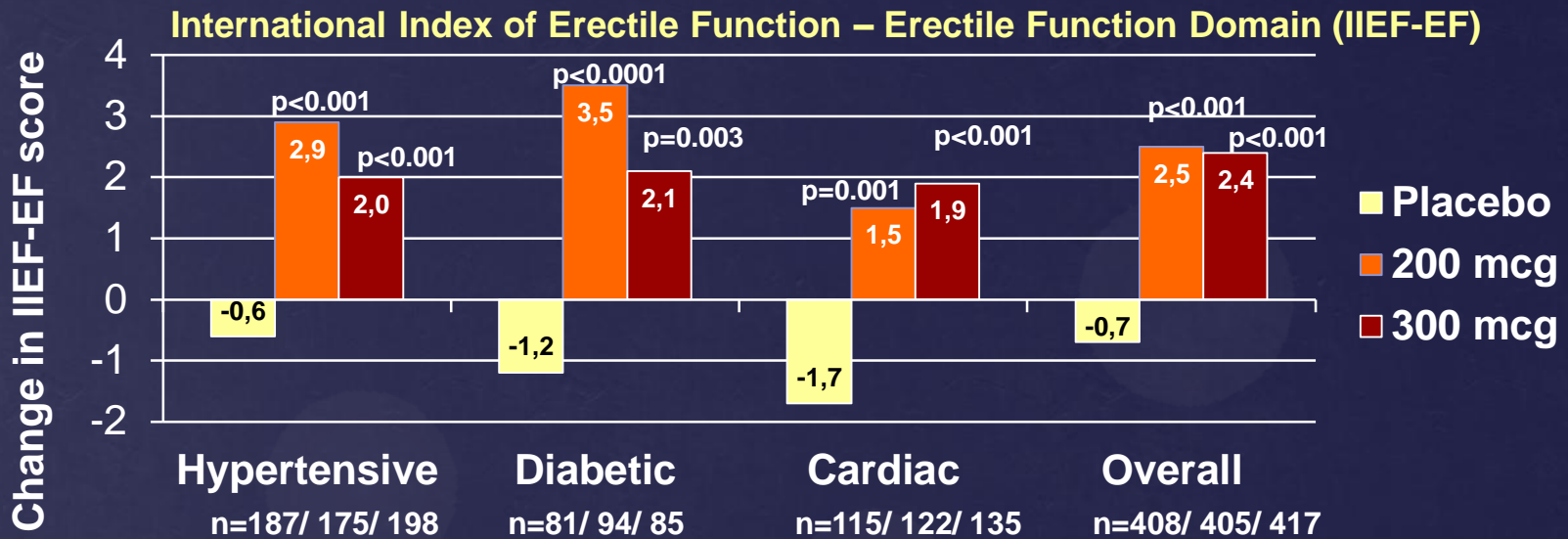
Primary Efficacy Endpoints

- Change from baseline in Erectile Function domain of IIEF
- Sexual Encounter Profile (SEP) Questions 2 and 3

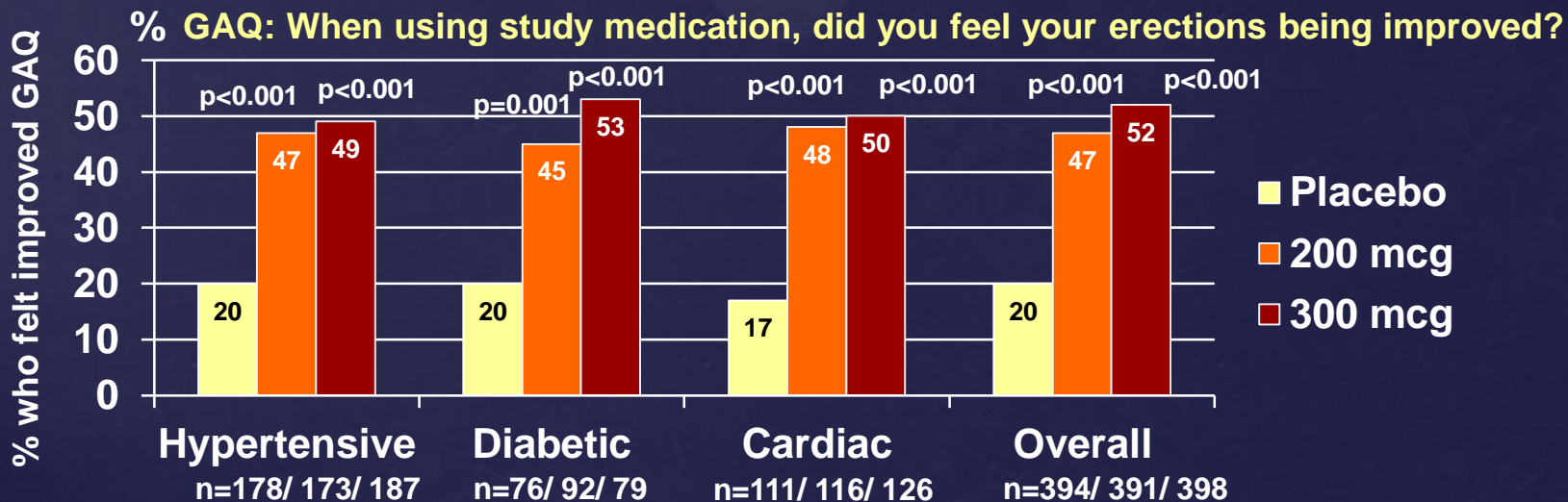
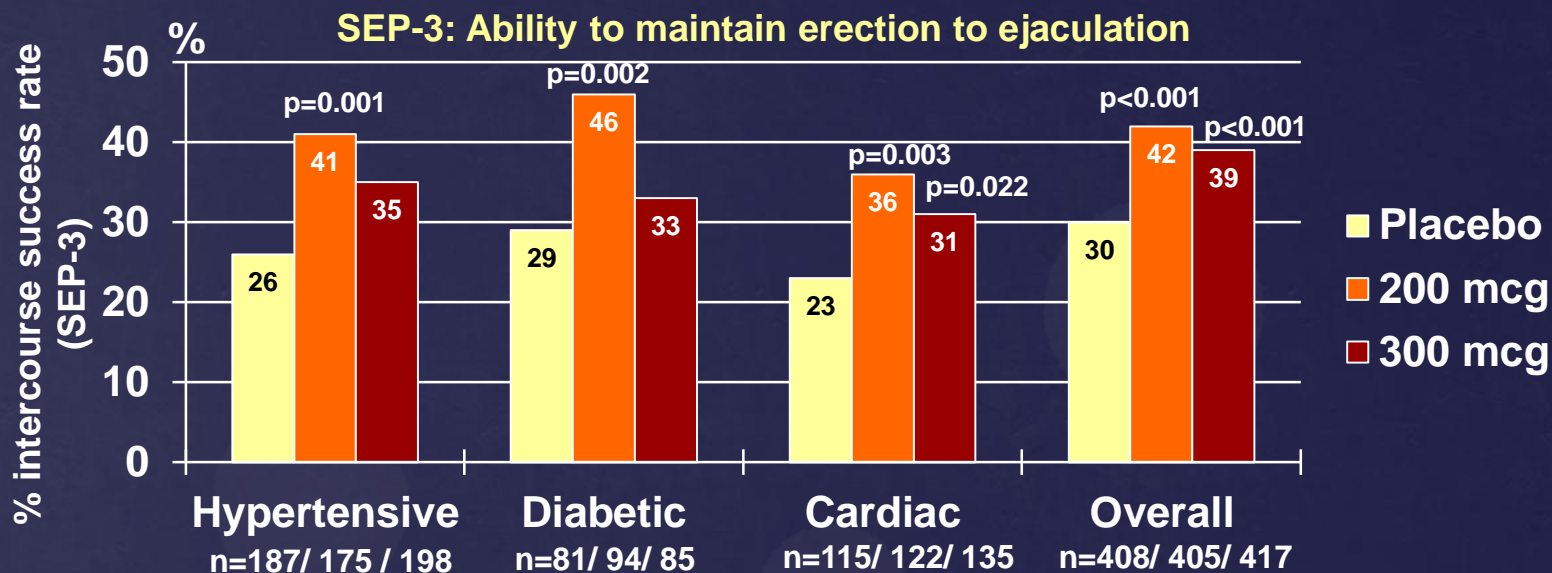
Secondary Efficacy Endpoint

- Global Assessment Question (GAQ)

Integrated Intent-To-Treat (ITT) Efficacy Analysis in Hypertensive, Diabetic and Cardiac Subpopulations (1)



Integrated Intent-To-Treat (ITT) Efficacy Analysis in Hypertensive, Diabetic and Cardiac Subpopulations (2)



VITAROS® Safety

Placebo
n=434

200 mcg
n=430

300 mcg
n=434

Patients with a least one drug related adverse event, n (%)

51(14)

178(41)

182(42)

Drug related serious adverse events

0

0

0

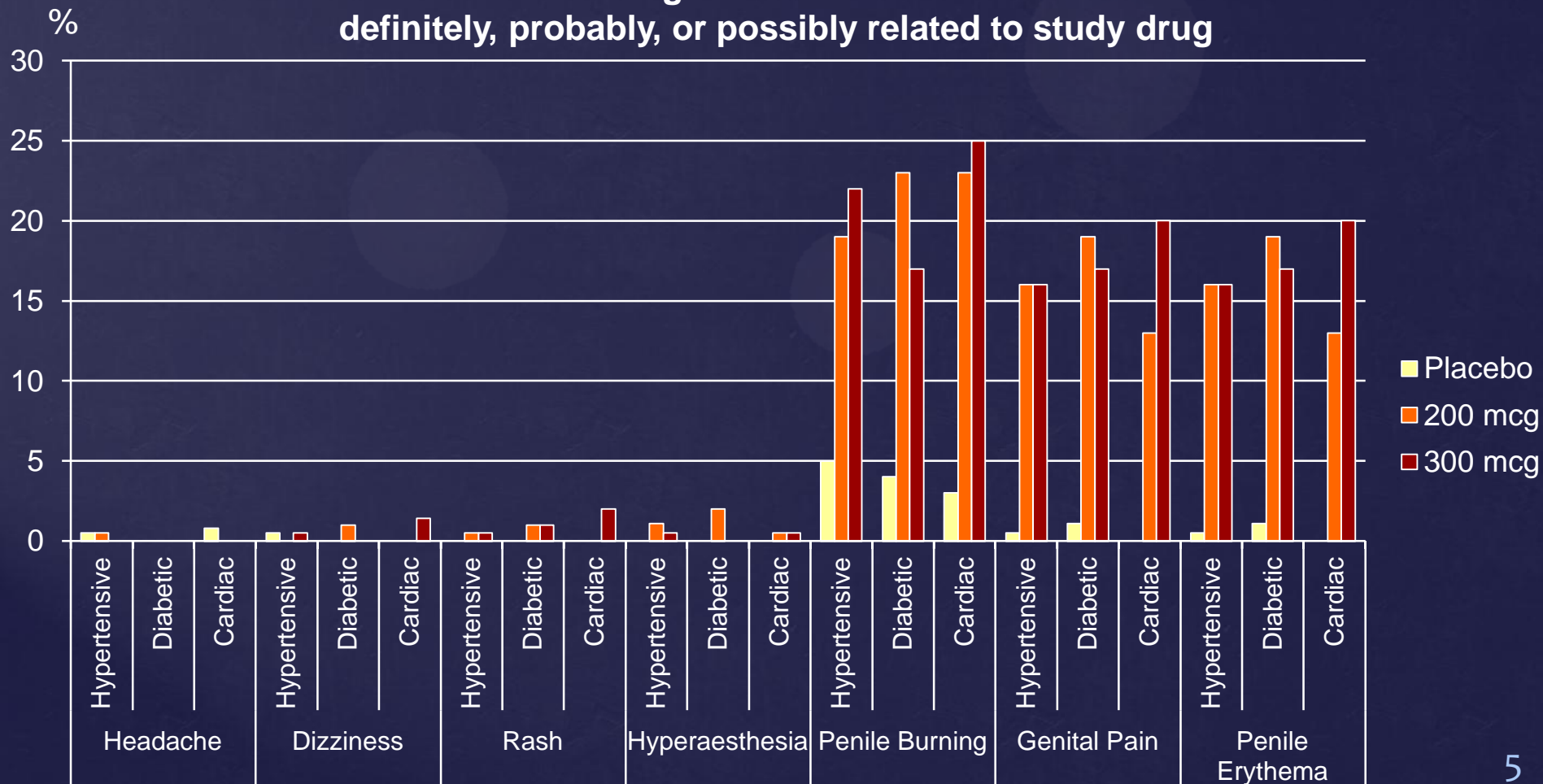
Patients withdrawn due to drug related adverse events, n (%)

0(0)

14(3)

25(6)

Treatment-emergent adverse events that were definitely, probably, or possibly related to study drug

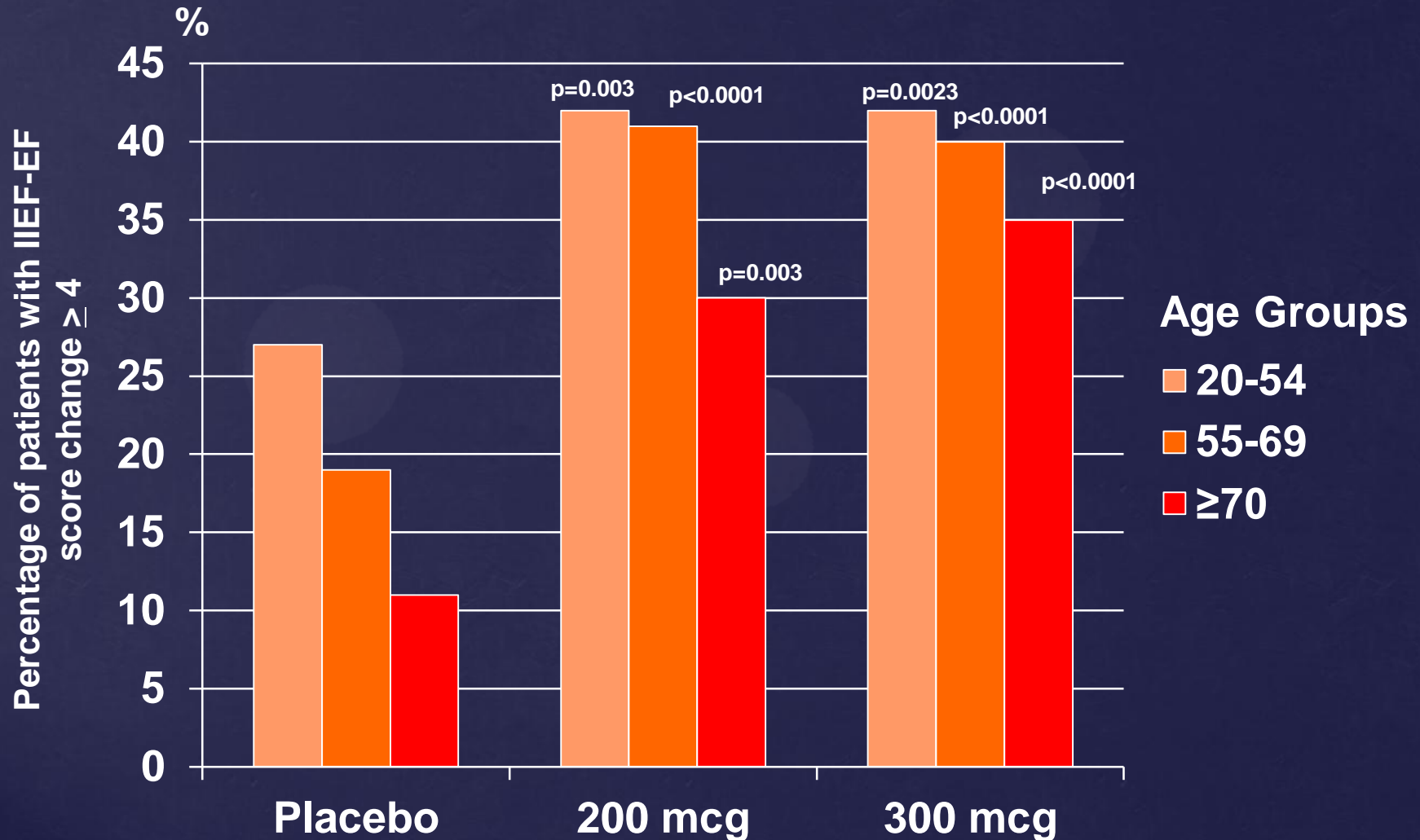


Conclusions

- VITAROS® demonstrated **statistically significant efficacy** across a broad range of ED severities and co-morbidities
- VITAROS® presents an **excellent safety profile**
 - No serious side effects
 - Most adverse events were localized to the site of application but were mild, short in duration and well tolerated
- VITAROS® shows the potential for **treating difficult to treat ED patients** such as those with hypertension, diabetes, and/or cardiac comorbidity...
 - ... it may offer a **1st choice treatment option for ED patients** of these specific categories as it is the case for every ED patient.

Back-Up: Age Group Analysis

Percent of Patients with IIEF-EF Change ≥ 4



Back-Up: Body Mass Index (BMI) Analysis

Percent of Patients with IIEF-EF Change ≥ 4

